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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/021,421	02/10/1998	RUSSEL T. JORDAN	397037	4431

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
12/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/021,421	JORDAN ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,14-21 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,14-21 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 5-7, 14-21, and 34-36 are presented for examination

Applicants' amendment filed 10/31/2007 and Information Disclosure Statement filed 10/30/2007 have been received and entered into the application. Accordingly, claims 1-2, 5, 6, 20-21, and 35 have been amended and claims 4 and 39-50 have been cancelled. Also, as reflected by the attached, completed copy of USPTO Form 1449 the cited references have been considered.

Applicants' arguments, filed 10/31/2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive.

Applicants' traverse the 35 U.S.C. 103 rejection of the claims as being obvious over EP 0 506 207 A2 in view of Applicants' disclosure at page 2.

Firstly, Applicants assert that EP '207 does not teach the use of 8-hydroxyquinoline, rather it teaches "**only** the use of halogenated and sulfated derivatives of 8-hydroxyquinoline" (Response, page 6) (emphasis added). Applicants further assert that 8-hydroxyquinoline is excluded from the list in EP '207 due to its relatively poor efficacy as a fungistat. The Examiner

respectfully reminds Applicants that he never indicated that EP '207 explicitly taught 8-hydroxyquinoline as an antifungal. Rather, EP '207 provides a non-exhaustive list of antifungal agents that may be used in the compositions disclosed therein. As disclosed by Applicants, 8-hydroxyquinoline is a known antifungal agent. As such, and particularly in view of the fact that the antifungals recited in EP '207 are not an exhaustive list, one skilled in the art would have been motivated by EP '207 to use any known antifungal agent, including 8-hydroxyquinoline as instantly claimed. Further, as evidenced by The Merck Index 12th Edition, 1996, Merck & Co., publ., pages 832 (Entry 4890), 8-hydroxyquinoline is a known "fungistat" used as an "antiseptic".

Secondly, Applicants arguments that the list of fungicides in EP '207 do not all behave in an equivalent manner as anticancer agents is not pertinent to the present rejection. The recitation of functional limitations such as "...for use in treating epithelial lesions..." (*e.g.*, claim 1) and "...the composition being a pharmaceutical grade material having a capacity for treating at least one type of lesion...." (*e.g.*, claim 1) are not given patentable weight because a composition is being claimed, not a method of treatment. As such, the fact that the list of fungicides in EP '207 may not act as anticancer agents has no bearing on the present rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-3, 5-6, 14-15, 19-21, and 34-36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 0 506 207 A2 (Published 9/30/1992) (prior art of record) in view of Applicants' disclosure at page 2.

EP '207 discloses the use of water-soluble zinc-containing compounds in topical pharmaceutical compositions containing pharmacologically active agents to enhance the skin or mucous membrane penetration and retention of the pharmacologically active agent (Abstract). The preferred water-soluble zinc-containing compounds include zinc chloride as recited in the instant claims (page 2, lines 42-43). Said water-soluble zinc-containing compounds are disclosed to dissociate in the topical vehicle so as to provide zinc ions for complexation or chelation with the pharmacologically active agents present in the vehicle (page 3, lines 10-12). Zinc-containing compounds are preferably present in an equimolar ratio with the pharmacologically active agents, thus meeting the limitation of instant claims 2-3 (*id.* at lines 24-25). With respect to the instantly claimed concentration of 8-hydroxyquinoline of at least 5 percent, it would have been obvious to use the same amount of active agent as the amount of the zinc-containing compound because the reference discloses equimolar ratios. Normally, use of equimolar amounts of a zinc-containing compound and pharmacologically active agent will not involve the use of escharotic amounts of zinc chloride and less than 35% zinc chloride is

disclosed to be an upper limit when no escharotic effect is desired (*id.* at lines 28-31). This upper limit meets the limitation "ranging up to forty percent by weight" as recited in instant claim 5 and "less than an amount that produces an eschar in healthy mammalian tissues" as recited in instant claim 1. Other ingredients, including stability-enhancing agents and antioxidants may be added to the disclosed compositions (*id.* at lines 35-36). The reference thus reasonably suggests the addition of antioxidants such as nordihydroguiaretic acid and ascorbic acid as recited in instant claims 19-21, and 34-36. With respect to the addition of the instantly claimed 8-hydroxyquinoline, EP '207 suggests that antifungal agents are suitable pharmacologically active agents for use in the disclosed compositions (page 4, lines 9-31). While 8-hydroxyquinoline is not recited in the list of antifungal agents in EP '207, it is noted that Applicants disclose at page 2, lines 3-22 of their specification that 8-hydroxyquinoline is a known antifungal agent and chelating agent (see especially lines 12-14). Thus, it would have been obvious to one of ordinary skill in the art to use 8-hydroxyquinoline as an antifungal agent in the compositions disclosed in EO '207. With respect to the carriers recited in claims 14-15, the reference discloses that typical carriers include water, gel-producing materials, propylene glycol, sorbitol, etc. (page 5, lines 40-43).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to formulate a composition comprising 8-hydroxyquinoline and a chelatable metal agent such as zinc chloride. The motivation to do so is found throughout EP '207 wherein compositions comprising zinc chloride and pharmacologically active agents, including antifungal agents, are disclosed. As such, it would have been obvious to one of ordinary skill in the art that any antifungal agent, including the instantly claimed 8-

hydroxyquinoline, could have been reasonably incorporated into the compositions disclosed in EP '207. Applicants' discovery that compositions comprising 8-hydroxyquinoline and zinc chloride can be used to treat epithelial lesions does not constitute a patentable distinction over the compositions disclosed in the reference. This is because a composition comprising 8-hydroxyquinoline and zinc chloride, as reasonably suggested and motivated by EP '207, is capable of performing the use recited in the instant claims.

Claims 16-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 0 506 207 A2 (Published 9/30/1992) (prior art of record) in view of Applicants' disclosure at page 2 as applied to claims 1-3, 5-6, 14-15, 19-21, and 34-36 above, and further in view of The Merck Index 12th Edition, 1996, Merck & Co., publ., pages 551 & 925-926.

EP '207 discloses as discussed *supra*. The Merck Index is provided as evidence that lecithin is an edible and digestible surfactant and emulsifier of natural origin used in pharmaceuticals and cosmetics (page 926). Further, dimethyl sulfoxide is disclosed as a penetrant carrier to enhance absorption (page 551). Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art to use lecithin and/or dimethyl sulfoxide in a carrier for pharmaceutically active agents. The skilled artisan would reasonably expect that lecithin and/or dimethyl sulfoxide would be effective in increasing the absorption of the topical compositions disclosed in EP '207.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

December 18, 2007

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